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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,124	04/23/2007	Harry J. Klee	UF.386CXC1	5548

23557 7590 10/11/2011  
SALIWANCHIK, LLOYD & EISENSCHENK  
A PROFESSIONAL ASSOCIATION  
PO Box 142950  
GAINESVILLE, FL 32614

EXAMINER
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KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
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1638

NOTIFICATION DATE	DELIVERY MODE
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10/11/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

euspto@slepatents.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/574,124	KLEE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	RUSSELL KALLIS	1638	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2011.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 5) ☒ Claim(s) 18,34,36,47,58 and 94-113 is/are pending in the application.
- 5a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 18,34,36,47,58,94 and 105-113 is/are rejected.
- 8) ☒ Claim(s) 95-104 is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                          |

### **DETAILED ACTION**

Those rejection under 112 1<sup>st</sup> paragraph enablement is withdrawn in view of Applicants' arguments.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 18, 34-36, 47, 58 and 94-113 are pending and examined.

### ***Claim Rejections - 35 USC § 112***

#### ***Written Description***

Claims 18, 34, 36, 47, 58, 94 and 105-113 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a polynucleotide construct comprising a plant phenylalanine decarboxylase enzyme coding sequence, expression constructs thereof, cells and a plant transformed therewith, and a method thereof for increasing the flavor or fragrance in a plant.

Applicants describe SEQ ID NO: 4, 6, 8 and 12 encoding SEQ ID NO; 5, 7, 9 and 13 respectively from tomato species encoding phenylalanine decarboxylase enzymes.

Applicants do not describe any conserved features required for activity of the broadly claimed genus of phenylalanine decarboxylases or a representative number of

sequences of phenylalanine decarboxylase enzymes and their respective coding sequence from the broadly claimed genus of plant phenylalanine decarboxylase sequences.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. The court stated that, “A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.” *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of phenylalanine decarboxylase enzymes sequences. Applicants only describe SEQ ID NO: 4, 6, 8 and 12 encoding SEQ ID NO: 5, 7, 9 and 13 respectively from tomato species encoding phenylalanine decarboxylase enzymes. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of phenylalanine decarboxylase enzymes sequences. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for phenylalanine decarboxylase activity, it remains unclear what features identify a phenylalanine decarboxylase enzyme. Since the genus of phenylalanine decarboxylase enzymes sequences has not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims. Further, the limitation of the source of the polynucleotide sequences in Claim 94 does not further describe the sequences of claim 18 because it does not teach any structure for the claimed function.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18, 34-36 and 105-106 are rejected under 35 U.S.C. 102(b) as being anticipated by Maldonado-Mendoza, I. *et al.* Plant Physiology (1996) Vol. 110: pp. 43-49.

The claims are broadly drawn to a polynucleotide construct comprising a polynucleotide encoding a decarboxylase active on phenylalanine, a cell transformed therewith, and a plant bred to contain the polynucleotide encoding the decarboxylase active on phenylalanine.

Maldonado-Mendoza teaches *TyDC5* gene from opium poppy expressed in *E. coli* having activity on phenylalanine; wherein the said source of the *TyDC5* gene, the opium poppy plant, expresses said decarboxylase active on phenylalanine (see page 46 in column 1 lines 6-13 and in Table 1).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18, 34-36, 47, 58 and 105-113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maldonado-Mendoza, I. *et al.* Plant Physiology (1996) Vol. 110: pp. 43-49 in view of itself.

The claims are broadly drawn to a polynucleotide construct comprising a polynucleotide encoding a decarboxylase active on phenylalanine, a cell transformed therewith, and a plant bred to contain the polynucleotide encoding the decarboxylase active on phenylalanine; and methods of expressing the polynucleotide encoding the decarboxylase active on phenylalanine in a plant.

Maldonado-Mendoza teaches *TyDC5* gene from opium poppy expressed in *E. coli* having activity on phenylalanine; wherein the said source of the *TyDC5* gene, the opium poppy plant, expresses said decarboxylase active on phenylalanine (see page 46 in column 1 lines 6-13 and in Table 1); and transformation of tobacco with the *TyDC5* promoter to study expression patterns of the gene (page 46 column 1 second full section and Tables II and III).

It would have been obvious at the time of filing to transform tobacco with the *TyDC5* gene of opium poppy for research to investigate the expression of *TyDC5* in both tobacco, to study the role of alkaloids in early development, and in plants that do not produce isoquinoline alkaloids, to investigate additional roles of *TyDC* genes in plants (see paragraph spanning column 1 and 2 of page 48). One of ordinary skill would have been motivated by the teachings of Maldonado-Mendoza that the role of alkaloids in early development is important research topic and that production of alkaloids by transgenic engineering of plants is of great value in the biotech industries; and would have a reasonable expectation of success in transforming a plant with the polynucleotide

encoding the decarboxylase active on phenylalanine given the availability of the *TyDC5* gene and the success of Maldonado-Mendoza in transforming tobacco with the promoter of the *TyDC5* gene; wherein the choice of promoter is an obvious design choice in engineering a plant to express a polynucleotide.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Claims 18, 34, 36, 47, 58, 94 and 105-113 are rejected.

Claims 95-104 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 1638

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RUSSELL KALLIS whose telephone number is (571)272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Russell Kallis/  
Primary Examiner, Art Unit 1638